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By: JM Smoler

PATENT

Attorney Docket No.: 018563-004920US

Client Ref. No.: AT00106.2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

MUHAMMAD CHISHTI *et al.*

Application No.: 10/788,510

Filed: February 27, 2004

For: SYSTEM AND METHOD FOR
POSITIONING TEETH

Confirmation No. 7442

Examiner: WILSON, John J.

Tech Center/Art Unit: 3732

declaration UNDER

37 C.F.R. § 1.132

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, Robert L. Boyd, hereby declare that:

1. I am a licensed Orthodontist and the Chair of the Department of Orthodontics for the University of the Pacific, Arthur A. Dugoni School of Dentistry in San Francisco, California. I received a Doctorate in Dental Surgery from Temple University Dental School in 1970, a Certificate in Periodontics from the University of Pennsylvania, School of Dental Medicine, in 1972, and a Certificate in Orthodontics from the University of Pennsylvania, School of Dental Medicine, in 1974. From 1974 to the present I have been engaged in the clinical practice of orthodontics. I have published more than 100 scientific articles relating to orthodontics and have given more than 375 continuing education courses and essays/lectures to dental groups around the world. A copy of my Curriculum Vitae is attached.

2. It is my understanding that U.S. Patent Application No. 10/788,510 ("the '510

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application) was filed on February 27, 2004 and that the '510 application is a continuation application that claims priority to an application filed on October 8, 1998. Thus, I have been informed that the date of reference relative to the knowledge and practices of one of ordinary skill in the art is October 8, 1998.

3. In October 1998, I was aware of the general practices of orthodontists and had personal experience with orthodontic treatment using braces and patient removable dental appliances.

4. It is my understanding that the '510 application is currently under *ex parte* examination before the United States Patent and Trademark Office ("USPTO") and that the USPTO has issued a Final Office Action in the above-referenced matter.

5. It is my understanding that a Response to Final Office Action ("Response") has been prepared for filing in the reexamination.

6. Based on my reading of the '510 application, it is my opinion that a person of ordinary skill in the art is an orthodontist with at least several years of experience in a practice limited to orthodontics.

7. I am aware that Claim 2, as presented in the Response, states:

"2. A method for fitting a set of upper and lower teeth in a masticatory system of a patient, comprising:

modeling a set of upper and lower teeth in a masticatory system of a patient in three or more predetermined positions prior to a stage of treatment; and

generating a patient removable appliance for each of the three or more predetermined positions, said appliance having cavities and wherein the cavities of successive ones of the plurality appliances have different geometries shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, wherein said stage of treatment comprises successively applying the appliances to the patient's teeth."

8. Prior to October 8, 1998, the practice of orthodontics was reactionary. By that,

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what I mean is that the approach followed by orthodontists with typical braces was to apply a force to teeth (via wire braces and brackets), and after a period of time examine the resulting movement and positions of the patient's teeth. After the examination, the orthodontist would determine what new set of forces to apply to the teeth to further move the teeth as desired by the orthodontist. Prior to examining this "resultant" position of the teeth, the orthodontist would not have specific knowledge of what forces he would want to employ to further move the teeth, or when to employ those forces. Accordingly, it is my opinion, that, prior to October 8, 1998, in keeping with the reactionary procedures of orthodontists, an orthodontist would determine the next stage of movement of a patient's teeth after examining the results of the previous stage. Certainly, then, an orthodontist would not have generated a subsequent tooth arrangement prior to generating a tooth arrangement of a preceding stage.

9. Paragraph 8 above discusses the traditional reactionary practices of orthodontics. In addition, prior to October 8, 1998, traditional practice with respect to orthodontic treatment using patient removable dental appliances, such as polymeric shell appliances, was reactionary by generally consisting of:

- (i) examining the patient;
- (ii) fabricating an appliance using a physical model of the patient's teeth (e.g., a plaster mold) and a vacuum forming machine;
- (iii) prescribing that the patient wear the appliance;
- (iv) after a period of time, examining the resulting movement and positions of the patient's teeth; and
- (v) fabricating, if necessary, another appliance using a physical model of the patient's teeth.

Certainly, then, an orthodontist would not have fabricated a subsequent appliance before examining the resulting movement and position of the patient's teeth. And an orthodontist would not have modeled teeth to produce a subsequent appliance before applying a previous appliance and examining the resulting movement and repositioning of the teeth at a previous stage. Consequently, it is my opinion that a person of ordinary skill in the art would not have modeled

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a set of upper and lower teeth in a masticatory system of a patient in three or more predetermined positions, and then generated a patient removable appliance for each of the three or more predetermined positions, where the modeling is accomplished prior to successively applying the appliances to the patient's teeth to reposition the teeth from one arrangement to a successive arrangement, as provided in Claim 2.

10. I am aware that Claim 3, as presented in the Response, states:

"3. A method for fitting a set of upper and lower teeth in a masticatory system of a patient, comprising:

modeling a set of upper and lower teeth in a masticatory system of a patient using three or more predetermined molds or casts prior to a stage of treatment; and

generating a patient removable appliance having cavities for each of the three or more molds or casts, said appliance having cavities and wherein the cavities of successive ones of the plurality appliances have different geometries shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, wherein said stage of treatment comprises successively applying the appliances to the patient's teeth.

11. Paragraphs 8 and 9 above discusses the traditional reactionary practices of orthodontics with respect to dental appliances. Consequently, it is my opinion that, prior to October 8, 1998, a person of ordinary skill in the art would not have modeled a set of upper and lower teeth in a masticatory system of a patient using three or more predetermined molds or casts, and then generated a patient removable appliance having cavities for each of the three or more molds or casts, where the modeling is accomplished prior to a successively applying the appliances to the patient's teeth to reposition the teeth from one arrangement to a successive arrangement, as provided in Claim 3.

12. I am aware that Claim 25, as presented in the Response, states:

"25. A method for generating appliances for repositioning a set of upper and lower teeth in a masticatory system of a patient, comprising:

modeling a set of upper and lower teeth in a masticatory system of a patient prior

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to a stage of treatment, the modeling comprising modeling the set of teeth in an initial position, a desired position, and a plurality of intermediate positions; and

generating a patient removable appliance for each of at least two of the intermediate positions, each patient removable appliance having cavities and wherein the cavities of successive appliances of the plurality have different geometries shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, wherein said stage of treatment comprises successively applying the appliances to the patient's teeth."

13. Paragraphs 8 and 9 above discusses the traditional reactionary practices of orthodontics with respect to dental appliances. Consequently, it is my opinion that, prior to October 8, 1998, a person of ordinary skill in the art would not have modeled a set of upper and lower teeth in a masticatory system of a patient in an initial position, a desired position, and a plurality of intermediate positions, and then generated a patient removable appliance for at least two of the intermediate positions, where the modeling is accomplished prior to successively applying the appliances to reposition the teeth from one arrangement to a successive arrangement, as provided in Claim 25.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: Oct 19, 2006

By: Robert L. Boyd
Robert L. Boyd

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